September 6, 2005

NDI Submission for Kakadu Plum Concentrate

1.0 Product Description

Kakadu Plum Concentrate is the new dietary ingredient produced by Access Business Group L.L.C. (ABG) and intended for use in dietary supplements in the United States.

1.1 Kakadu Plum

The kakadu plum is a fruit from a tree localized in the northern regions of the Northern Territories, Queensland, and Western Australia. The small olive-sized fruit consists of a hard, woody seed covered by a layer of edible flesh. The kakadu plum is harvested from early March through June, depending on the severity and extent of the monsoon season.

ABG's Kakadu Plum Concentrate is a spray-dried concentrate of a water extract of kakadu plums. ABG's product contains no less than 15% Vitamin C, and may contain as much as 45% Vitamin C. ABG's Kakadu Plum Concentrate was approved by the Australian Therapeutics Goods Administration (TGA) in December 2003. See *Commonwealth of Australia Gazette* notice in Appendix 1.

1.2 Common Names

Kakadu Plum, Billy Goat Plum, Green Plum, Salty Plum, Wild Plum, murunga (Aboriginal), manmohpan (Aboriginal), marnybi (Aboriginal).

1.3 Scientific Names

Terminalia ferdinandiana(Excell) is the scientific name for the tree from which the kakadu plums used to produce Kakadu Plum Concentrate are harvested. (Australian National Herbarium, 2004). The trees grow in the Northern Territory and Western Australia, and to a limited extent in Darwin (Wrigley, 1988).

1.4 Physical and Chemical Properties

Aspect:	Dry Powder
Color:	Ranges from medium-tan to dark-tan/light brown.
Odor:	Slight caramelized aroma.
Taste:	Tart, with slight salty, astringent, and bitter components.
Solubility:	Water Soluble
Particle size:	Minimum 100% through a USSS 40-mesh sieve.
Moisture:	Maximum 5% (LOD)
Hygroscopicity:	Hygroscopic; should be packaged and stored accordingly.
Vitamin C:	$\geq$15%

1.5 Product Specifications

ABG's Kakadu Plum Concentrate contains no less than 15% Vitamin C. The product meets appropriate food grade specifications. Further information regarding the specifications is provided in the confidential TGA report in Appendix 2. Confidential analyses of three batches of ABG's Kakadu Plum Concentrate evidencing compliance with specifications are also included in Appendix 3, together with the test methodologies and raw data (copies of the chemist's laboratory notebook pages).

1.6 Method of Manufacture

The kakadu plum fruit is harvested in the greater Darwin areas and is essentially free of extraneous materials including leaves, stems and all non-kakadu plum materials. The fruit is placed in a freezer at less than or equal to –20°C and kept at that temperature until processing.

The manufacturing process consists of milling, water extraction and enzyme treatment, pressing to recover juice, filtering to remove particulate matter, pasteurizing, and spray drying. All processing aids are either United States Pharmacopoeia (USP) or food grade substances permitted for use in the production of foods and food ingredients. The extraction ratio range is 14 to 20 parts of fresh-frozen fruit to one part of finished extract powder. Additional details of the manufacturing method may be found in the confidential TGA report in Appendix 2.

1.7 Stability

The powder must be stored in sealed bags to prevent contamination with atmospheric moisture and microbial organisms. The powder is sealed in double polyethylene bags placed inside a fiber drum, which is the standard method of warehouse storage. The product must be stored under controlled room temperature conditions. Stability test data are summarized in the confidential TGA report provided in Appendix 2.

ABG's Kakadu Plum Concentrate product must be re-tested to verify adherence to product specifications after 12 months of storage. Subsequent testing must be done every six months since vitamin C concentration may decrease over time. As a result, long-term storage (>2 years) is not recommended.

2.0 Intended Use

The intended use of Kakadu Plum Concentrate is as a natural source of Vitamin C, similar to that of acerola cherry, rose hips, and blackcurrant extracts, in dietary supplements. Kakadu Plum Concentrate is formulated to deliver 150 - 450 mg Vitamin C per gram. ABG will supply Kakadu Plum Concentrate to dietary supplement manufacturers for use in supplement products in amounts consistent with current Vitamin C dietary supplement practices. Such products would reasonably be expected to deliver 100 - 800 mg Kakadu Plum Concentrate per day, providing a daily intake of 15 mg to 360 mg. Vitamin C under the ordinary conditions of intended use of the supplement.

3.0 Summary of Data and Information Supporting Safety

Support for safety relies on the existing approval by the Australian TGA and the history of human consumption of Kakadu plums long before 1994.

The Australian TGA (2003) determined that there is no evidence of any toxicity associated with the traditional use of the kakadu plum fruit and recent use of such food products. Moreover, the TGA concluded that, like the fruit, ABG's Kakadu Plum Concentrate is not expected to produce any toxicity after oral ingestion. The Australian TGA further concluded that "Kakadu Plum Concentrate appears suitable for adults, children, and pregnant and lactating women." A copy of the confidential TGA report is provided in Appendix 2.

Traditional dietary consumption by Australian Aborigines is described by Brand et al. (1982a, b), Porteus (1983), Isaacs (1987), Pain (1988), Brock (1993), Aboriginal

Communities of the Northern Territory (1993) and Peerzada et al. (1990). It is estimated that Aboriginals consume 100-200g of kakadu plums a week during the six months between March and August when the fruit is in season (The University of Sydney News, 1982). The fruit is particularly popular with Aboriginal children (Brand et al, 1982b; The University of Sydney News, 1982; Isaacs, 1987; Pain, 1988).

Contemporary use of kakadu plums in food products, such as jams, preserves, relishes, sauces, juices and ice cream flavoring, is described by Pain (1988), Graham and Hart (1997a, b), Woods (1998), Lindsay (2000), Vic Cherikoff Food Services (2001), Australian Food & Wine (2002) and Australian Culinary Consultants (2004). According to a recipe by Benjamin Christie, Australian Guest Chef and Consultant, there are 50g of kakadu plums in one liter of Kakadu Plum and Chili Sauce (Christie 2004). Based on a weight of 3 - 4g for a whole plum with pit, approximately 15 to 20 plums (without pits) would be present in a one liter bottle of sauce. If one-fifth of the bottle (200 gm) is used per serving, then an individual would consume three to four plums in a single serving of sauce. ABG estimates that daily servings of kakadu plum sauce may vary from 30g to 200g, equating to dietary intake of about one to six plums per day. The estimated amount of fruit in a 25g serving of kakadu plum jam is 8 - 16g, which equals 2 to 4 plums, assuming the jam contains 25% to 50% fruit. ABG's confidential discussion of the estimated kakadu plum intake from other widely available current recipes is provided in Appendix 4.

Analyses of kakadu plums show that the fruit contains one of, if not the, highest amount of vitamin C of any fruit, at 2,000 - 3,000 mg/100 g (Brand et al., 1982a,b; The Nutrition Gazette, 1982; Nutrition Today, 1983; Peerzada et al., 1990; Brock, 1993). Two commercially available kakadu plum products, a sauce and a jam, were recently analyzed by ABG and found to contain 0.34% and 0.51% Vitamin C, respectively. Results of the confidential analysis as well as the confidential methodology and copies of the chemists' notebooks are provided in Appendix 4. On a Vitamin C basis, one gram of Kakadu Plum Concentrate contains 150 - 450mg of Vitamin C and equates to approximately 4 to 5 kakadu plums.

Hegarty et al. (2001) analyzed kakadu plum fruit, representative of the fruit used to produce ABG's Kakadu Plum Concentrate, for cyanogenic glycosides and alkaloids. Fruit from one source showed negative in the test for alkaloids. Fruit from two sources contained less than 0.1 mg HCN per 100 grams of fruit. The reported values for oxalates, cyanogens and saponins in the kakadu plum fruit do not exceed those recorded for widely consumed foods, Miller and Woodrow (2004); Hegarty et al. (2001). The value for alkaloids is below that of common citrus fruits, Hegarty et al. (2001). ABG's Kakadu Plum Concentrate is a water extract of the fruit; however, it is expected that this extract would have similar properties in this respect to the whole fruit.

Kakadu Plum Concentrates containing 30% (Sample 3280) and 35% Vitamin C (Sample 2939) and representative of ABG's Kakadu Plum Concentrate, were also analyzed for cyanogens, alkaloids and oxalate by Miller and Woodrow (2004). They reported no detectable levels of cyanogens or alkaloids, and an oxalate concentration ranging from 25µg/g^{-1} (dry weight) to 64µg/g^{-1} (dry weight) for the Kakadu Plum Concentrate samples. Based on the highest detected amount of 64µg/g^{-1} oxalate in Kakadu Plum Concentrate, the maximum amount of oxalate ingested would be approximately 250mcg/4g dose, which is less than the oxalate content found in 1 whole kakadu plum (fruit) (based on analytical data range of 19851µg/g to 27563 µg/g (dry weight basis)) or 1/2630th of the amount of oxalate found in a 100g serving of spinach.

A scientific literature search was conducted by ABG on June 11, 2004 and again on August 29, 2005. A total of 29 citations were found for kakadu plum. None of these citations referred to any toxicity or adverse effects associated with the kakadu plum. Results of the literature searches are provided in Appendix 5.

Based on the above-described data and information, ABG has concluded that Kakadu Plum Concentrate when used as a natural source of Vitamin C, under ordinary conditions of intended use of dietary supplements, does not present an unreasonable or significant risk to safety and is reasonably expected to be safe.

4.0 Appendices

Appendix 1 - Australian TGA Listing for Kakadu Plum Concentrate

Appendix 2 - Office of Complementary Medicines, Therapeutic Goods Administration (2003). Evaluation of a new listable substance, *Terminalia ferdinandiana* (Kakadu plum). (Confidential unpublished TGA report).

Appendix 3 - Confidential Kakadu Plum Concentrate Analyses and Methods

Appendix 4 – Confidential "Kakadu Plum Products in the Market & Estimated Fruit Intake"

Appendix 5 - Results of scientific literature search

5.0 References

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